

DEC 22 2006

Attorney Docket No. 2004_2037A
Serial No. 10/519,536
December 22, 2006**REMARKS**

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

I. CLAIM STATUS AND AMENDMENTS

Claims 2-7 were pending in this application when last examined and stand rejected.

Support for the amendment to claims 2 and 6 can be found in the disclosure, for example, at page 13, lines 16-19.

No new matter has been added.

II. ENABLEMENT REJECTION

In item 7 on pages 3-4 of the Office Action, claims 4, 6 and 7 were again rejected under 35 U.S.C. § 112, first paragraph, on the basis the specification is only enabling for a method of treating chicken coccidiosis wherein the antibody is obtained from an egg of a chicken immunized with an antigenic outer membrane protein or an immunogenic fragment thereof having a common immunogenicity shared among sporozoite and merozoite of *Eimeria acervulina*, *Eimeria tenella*, and *Eimeria maxima* and is orally administered to a bird optionally in combination with a lactic acid bacterium and/or an antibody obtained from an egg of a chicken immunized with *Clostridium perfringens*, and not for a method of preventing chicken coccidiosis.

This rejection is respectfully traversed as applied to the amended claims.

The Office did not find the Rule 132 Declaration of July 5, 2006 persuasive. Applicants respectfully submit that the preventative effect of the antibody of the present invention was demonstrated in the previous Declaration for the reasons of record and for the following reasons.

The Office alleged that Wallach et al. teach that the one strain of *E. maxima* does not protect against challenge with a different strain of *E. maxima*.

In reply, kindly note that the above-mention Declaration described that "The farms were

Attorney Docket No. 2004_2037A
Serial No. 10/519,536
December 22, 2006

contaminated with Eimeria species.” The farms in which chicks were raised were contaminated not only with one strain of *E. maxima*, but with various *Eimeria* species, including *E. acerubulina*, *E. tenella* and *E. maxima*. A person skilled in the art would reasonably understand that a farm cannot be contaminated with only *E. maxima*, let alone with only one strain of *E. maxima*.

The Office also stated that the Declaration did not disclose challenge against *Eimeria* to demonstrate protection.

In reply, the Declaration described that “A broiler feed comprising Chick Start™ in an amount of 500 g/lit was administered to baby chicks until the chicks became 18 days old.” See page 1, item 2, second paragraph. The “baby chicks” had just been born and were not affected with coccidiosis. That is, the “baby chicks” were pathogen free birds. The Declaration demonstrated that the pathogen free baby chicks were raised in the farm contaminated with various *Eimeria* species, while being administered with the antibody of the present invention or Salinomycin, and the chicks were protected against coccidiosis.

In other words, in the experiments described in the Declaration, pathogen free birds were administered the claimed composition or salinomycin as a positive control. As a result, the birds in both groups were protected from coccidiosis. This Declaration demonstrates that the claimed composition is capable of inducing protective immunity against chicken coccidiosis.

Furthermore, attached herewith is a revised version of the Rule 132 Declaration for clarifying that “baby chicks” were pathogen free and that the farm was contaminated with *E. acerubulina*, *E. tenella* and *E. maxima*., i.e., various *Eimeria* species.

The Office stated that it is unclear how a percent of rate maturity is related to preventing coccidiosis.

In reply, it was described in the Declaration, “When Chicks are affected with coccidiosis, average weight and rate of maturity will greatly decrease, as a result, productivity will greatly decrease.” See page 2, lines 3-4 of the Declaration.

The chicks administered with the antibody of the present invention showed a high rate of maturity (94.6% or more), although they had been raised in the contaminated farm.

Attorney Docket No. 2004_2037A
Serial No. 10/519,536
December 22, 2006

If chicks are raised in a contaminated farm without any such protective agent, such a high rate of maturity would not be achieved, and as a result, most of the chicks would die. In this regard, please see attached reference Dalloul et al., Expert Rev. Vaccines, Vol. 5, No. 1, pp. 143-163, 2006.

Please note that a comparative experiment wherein no agent is administered cannot be conducted, because once such an experiment is conducted, a farm will be deeply contaminated and it will be very difficult to recover the farm after such contamination without the protection of the instant invention.

In view of the above, it is clear that the Declaration demonstrates that the claimed composition is capable of inducing protective immunity against chicken coccidiosis.

In view of the foregoing, favorable reconsideration and withdrawal of this ground of rejection is deemed to be appropriate.

Therefore, the rejection of claims 4, 6 and 7 under 35 U.S.C. § 112, first paragraph, is untenable and should be withdrawn.

III. WRITTEN DESCRIPTION REJECTION

In item 8 on pages 5-7 of the Office Action, claims 2-7 were newly rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification lacks written description support for the claimed "antigenic outer membrane protein" or an "immunogenic fragment thereof having a common immunogenicity."

It is respectfully submitted that the present invention overcomes this rejection by removing the objected to language. The objected language is replaced with "a soluble outer membrane protein of 18 to 27 kD from the merozoite of *Eimeria acervulina*" as clearly supported in the disclosure, for example, at page 13, lines 16-19.

Thus, the rejection is untenable and should be withdrawn.

DEC 22 2006

Attorney Docket No. 2004 2037A
Serial No. 10/519,536
December 22, 2006**CONCLUSION**

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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DEC 22 2006

NO. 7769 P. 9

Attorney Docket No. 2004_2037A
Serial No. 10/519,536
December 22, 2006

ATTACHMENTS

1. Revised Rule 132 Declaration; and
2. Expert Rev. Vaccines, Vol. 5, No. 1, pp. 143-163, 2006 (pp. 143 and 155 only).